UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,980	11/27/2001	John E. Carlson	2748 CON	2946

50855 7590 10/14/2005

UNITED STATES SURGICAL,
A DIVISION OF TYCO HEALTHCARE GROUP LP
150 GLOVER AVENUE
NORWALK, CT 06856

EXAMINER	
THALER, MICHAEL H	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/994,980	CARLSON ET AL.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-19,22-33 and 36-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19,22-33 and 36-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 25 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 25 and 39 are limited to the embodiment shown in figures 3-4C which includes tapered distal tip 60. However, in this embodiment, the expandable sleeve 52 is not in direct contact with the guidewire 54 since introducer 50 is located between these parts. Claim 25 ultimately depends from claim 16 which includes the limitation that the expandable sleeve is in direct contact with the guidewire. However, there is no basis in the original disclosure for the combination of these features in a single embodiment. Claim 39 ultimately depends from claim 30. The limitation "directly" in claim 30, line 5 is similarly inconsistent with embodiment defined in claim 39.

Claims 16-19, 22-33 and 36-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 25 and 39 are confusing and inaccurate for the reasons set forth above. In

claim 16, line 8, there is no antecedent basis for "the dilator". Note that claim 16 has been improperly amended since "the" (before "dilator") should have been underlined because it was not present in the claim immediately prior this amendment. In claim 30, lines 13-14, there is no antecedent basis for "the shaft". The outer tube of the dilator recited in claim 33 has already been recited in claim 30 as a sheath resulting in a double recitation of the same part.

Claims 16-19 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. (5,201,756) in view of Makower et al. (5,380,290). Horzewski et al. disclose the steps of positioning a radially expandable sleeve (e.g. 90 in figures 5A and 5B) in direct contact with and over a guidewire and inserting into the radially expandable sleeve a dilator 160 (figure 6C) to expand the sleeve (col. 13, lines 9-13). Horzewski et al. fail to disclose the step of forming a percutaneous tissue tract to the target vessel. However, Makower et al. teach that such a tissue tract should be formed (by needle 14) prior to the introduction of a guidewire therethrough apparently in order to obtain the advantage of facilitating the introduction of the guidewire. It would have been obvious to form a percutaneous tissue tract to the target vessel in the Horzewski et al. procedure so that it too would

have this advantage. As to claim 19, the radially expandable sleeve in the embodiment of figures 1A to 2F has an elastic structure so that its cross-section will collapse after expansion. As to claims 26-29, Horzewski et al. fail to disclose the claimed dimensions. However, it would have been obvious to so dimension the Horzewski et al. as claimed in order to fit within a blood vessel.

Claims 22, 30-33 and 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. (5,201,756) in view of Makower et al. (5,380,290) as applied to claims 16-19 and 23-29 above, and further in view of Dubrul et al. (5,431,676). Horzewski et al. fail to disclose the expandable sleeve comprising a tubular braid. However, it is old and well known in this art to construct expandable sleeves as tubular braids so that they expand smoothly. For example, Dubrul et al. teach that an expandable sleeve should be constructed as a tubular braid for this reason (col. 6, lines 40-61, col. 11, lines 25-29 and col. 12, lines 7-10) It would have been obvious to so construct the Horzewski et al. expandable sleeve so that it too would have this advantage. The expandable sleeve constructed as a tubular braid would retain its larger diameter after the dilator is removed when the outer layer is plastically deformable as indicated in col. 6, line 46-

48 of Dubrul et al. Alternatively, the expandable sleeve constructed as a tubular braid would retain its larger diameter after the dilator is removed when the outer tube of the dilator to remains in place as explained in the analysis regarding claim 33 as follows. As to claims 30 and 33, Horzewski et al. fail to disclose using an outer tube of the dilator to remain in place after the dilator is removed to maintain the large diameter of the sleeve. However, it is old and well known in this art to so construct dilators (as admitted by applicant on page 5, lines 32-33) so that the main portion of the dilator can be removed leaving the outer tube or sheath in place. It would have been obvious to so construct the Horzewski et al. dilator so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03).

Applicant's arguments filed Sep. 9, 2005 have been fully considered but they are not persuasive. Contrary to applicant's remarks, Horzewski et al. disclose the steps of positioning a radially expandable sleeve 90 in direct contact with and over a guidewire and inserting into the radially expandable sleeve a dilator 160 to expand the expansible sleeve to provide an access lumen to the blood vessel. After dilator 150 is withdrawn, as described in col. 13, lines 3-5, the guidewire remains in the

patient. At this point, the expandable sleeve 90 is positioned directly over the guidewire such that it is in direct contact with the guidewire as claimed. Then, when dilator 160 is inserted into the sleeve 90 and thus into the patient, as described in col. 13, lines 9-13, it is clearly inserted over the guidewire. Note also that dilator 160 has a central lumen to accept the guidewire.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael

Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

mht
10/7/05

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731